

REMARKS

Claims 1-12 were pending. Claims 3-6 and 9-12 have been canceled. Therefore, claims 1, 2, 7 and 8 are pending upon entry of this amendment.

Rejection of Claims 1, 2, 7 and 8 under 35 U.S.C. § 103(a)

Claims 1, 2, 7 and 8 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Jennings (WO 094/17794), in view of Coffin (U.S. 5,492,930). Applicants respectfully traverse this rejection.

Applicants' claims are directed to methods of treating a subject afflicted with amyotrophic lateral sclerosis, by administering to the subject an amount of creatine or creatine phosphate.

According to the Examiner, Jennings describes "compositions comprising amounts of creatine and creatine phosphate for use in treating wasting diseases." Jennings describes the use of compositions comprising a sugar and glycine derivatives to enhance cardiac tissue formation. Jennings does not teach or suggest the use of creatine or creatine phosphate to treat amyotrophic lateral sclerosis, as claimed by Applicants.

Coffin fails to overcome the deficiencies of Jennings. Coffin is directed to a method for treating central nervous system disorders and improving cognitive ability in mammals, by using 2-phenyl-1,3-propanediol monocarbamate-not creatine or creatine phosphate. In fact, Coffin does not even describe the use of 2-phenyl-1,3-propanediol monocarbamate to treat amyotrophic lateral sclerosis. ALS is only mentioned in the background section when describing the teachings of a prior art publication, EP 0 531 105 A1. This publication describes the use of felbamate for treating "Guam ALS, Parkinson's disease, Alzheimer's disease, dementia and lathrism." Coffin distinguishes his compound, 2-phenyl-1,3-propanediol monocarbamate over felbamate by stating that it has a different physiological effect than felbamate and "its action is uniquely different from felbamate."

An ordinarily skilled artisan would not have been motivated to combine the teachings of Coffin with Jennings because one of ordinary skill in the art would appreciate that each disease has unique characteristics. One of ordinary skill in the art would not be motivated to combine the teachings of Jennings and Coffin because an ordinarily skilled artisan would have no expectation of success. While Coffin teaches that to treat certain neurodegenerative disorders it may be useful to reverse deficits resulting from a loss of cholinergic or NMDA receptor function, there is no teaching or

suggestion in Jennings that creatine or creatine phosphate fulfills this role or would treat the disease.

Therefore, Applicants respectfully request that this rejection of claims 1, 2, 7, and 8 under 35 U.S.C. § 103 (a) be reconsidered and withdrawn.

Rejection of Claims 1, 2, 7 and 8 under 35 U.S.C. § 103(a)

Claims 1, 2, 7 and 8 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Jennings (WO 094/17794), in view of Flohe (U.S. 4,788,179). Applicants respectfully traverse this rejection.

Applicants' claims and Jennings are described above.

Flohe is directed to the use of dipeptide compounds for the treatment of amyotrophic lateral sclerosis. Flohe does not teach or suggest the use of creatine nor creatine phosphate for the treatment of amyotrophic lateral sclerosis. According to the Examiner, Flohe "teaches the use of a peptide mendicant that resulted in an improvement of muscle weakness in an ALS patient." Flohe notes that in ALS "the patient's intellect remains clear."

The present invention would not have been obvious to an ordinarily skilled artisan in view of Jennings and Flohe. Jennings is directed to enhancing cardiac tissue formation for patients suffering from dementias. Jennings does not teach or suggest methods for treating ALS, let alone treating ALS with creatine or creatine phosphate, as claimed by Applicants.

Flohe fails to overcome the deficiencies of Jennings. In particular, Flohe merely teaches the use of dipeptide derivatives for the treatment of ALS, and does not teach or suggest the use of creatine or creatine phosphate. An ordinarily skilled artisan would not be motivated to combine the teachings of Flohe with the teachings of Jennings because the teachings of Flohe are directed to the use of a particular class of compounds, which does not include creatine nor creatine phosphate. While Flohe noted that there was some improvement in muscle weakness when the dipeptide compounds were administered, an ordinarily skilled artisan would appreciate that these observations would pertain only to the compounds actually tested and claimed by Flohe. Furthermore, one of ordinary skill in the art would also appreciate that the improvement in muscle weakness may be indicative of an improvement in the rate of neurodegeneration and not simply and improvement in one symptom. Jennings merely teaches that combinations of creatine and sugar may be useful for enhancing tissue formation. It would not be obvious to one of ordinary skill in the art that these compounds could be used to treat amyotrophic

lateral sclerosis, merely because the compounds described are alleged to treat one symptom of the disease.

Therefore, Applicants respectfully request that this rejection of the claims under 35 U.S.C. § 103 (a) be withdrawn.

Provisional Rejection of Claims 1, 2, 7 and 8 under Non-Statutory Obviousness Type Double Patenting

Claims 1, 2, 7, and 8 have been provisionally rejected under non-statutory obviousness type double patenting over claims 1-4, 7,8 and 13 of copending application 10/718,765.

Applicants disagree. Claims 1-4, 7, 8, and 13 of copending application 10/718,765 are directed to methods for treating a subject afflicted with a nervous system disease. The method includes administering to the subject an amount of creatine, creatine phosphate or a creatine analog or a salt thereof sufficient to prevent, reduce, ameliorate or eliminate the disease.

Applicants' claims non-obvious over the invention described in claims 1-4, 7, 8 and 13 of U.S.S.N. 10/718,765, because the presently claimed invention is a patentably distinct sub-genus. In particular, as described in Applicants' specification, Applicants' have found that the use of creatine and creatine phosphate are particularly advantageous for the treatment of amyotrophic lateral sclerosis. Therefore, Applicants respectfully request that this rejection of the claims under non-statutory obviousness type double patenting be withdrawn.

SUMMARY

Cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's objections and/or rejections. The cancellation of claims are being made solely to expedite prosecution of the above-identified application. Applicants reserve the option to further prosecute the same or similar claims in the present or another patent application.

U.S.S.N. 10/718,846
Attorney Docket No.: AVZ-001CPUSCN

Examiner: M. L. Shibuya
Group Art Unit: 1639

In view of the remarks set forth above, it is respectfully submitted that this application is in condition for allowance. If there are any remaining issues or the Examiner believes that a telephone conversation with Applicants' Attorney would be helpful in expediting prosecution of this application, the Examiner is invited to call the Elizabeth A. Hanley, Esq. at (617) 227-7400.

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